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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,870	10/784,870 02/24/2004		Mikio Takaiwa	249142US0DIV 1309	
22850	7590	06/12/2006		EXAM	MINER
OBLON, S	•	MCCLELLAND, I	RAO, MANJUNATH N		
ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER	
	,			1652	<u> </u>

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/784,870	TAKAIWA ET AL.				
Office Action Summary	Examiner	Art Unit				
	Manjunath N. Rao, Ph.D.	1652				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING ID.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION .136(a). In no event, however, may a reply be timed will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONEI	l. ely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>05 l</u> 2a)□ This action is <b>FINAL</b> . 2b)⊠ Thi      3)□ Since this application is in condition for allowed closed in accordance with the practice under	is action is non-final. ance except for formal matters, pro					
Disposition of Claims						
4) ⊠ Claim(s) <u>7-34</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>7-34</u> is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/	awn from consideration.					
Application Papers						
9)☑ The specification is objected to by the Examin 10)☑ The drawing(s) filed on 24 February 2004 is/a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11)☐ The oath or declaration is objected to by the E	re: a)⊠ accepted or b)□ objected or b)□ objec	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No. 09/920,954.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da	ite				
<ol> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date <u>2/04</u>.</li> </ol>	5)	atent Application (PTO-152) <u>anments(2 p)</u> .				

### **DETAILED ACTION**

Claims 7-34 are currently pending in this application.

## **Drawings**

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

## Specification

Examiner notes that applicants have not updated the relationship of the instant application to its parent application that has matured in to a US patent. Examiner urges applicants to amend said information by providing the US patent number in response to this Office action.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18 and 32 are drawn to the same biological deposits. However each claim claims that the polynucleotide in these biological deposit are different. For example the biological deposit of claim 18 indicates it comprises the polynucleotide which encodes the polypeptide with SEQ ID NO:1 which that of claim 32, claims a deposit comprising

polynucleotide encoding SEQ ID NO:2. It is not clear to the Examiner as to how a single deposit can comprise two different polynucleotides. Examiner requests clarification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 32 are rejected because the invention appears to employ microorganisms transformed with novel polynucleotides. Since the microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed microorganisms' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The specification does not disclose a repeatable process to obtain the microorganisms and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these microorganisms should have been made in accordance with 37 CFR 1.801-1.809. In order for the claims to be enabled, applicants must show that either the microorganisms can be made by publicly available materials or that the microorganisms as such has been deposited in such a way that it is freely available to the public. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmids and the host cells that are transformed using said plasmids.

It appears that applicants have made a deposit under the terms of the Budapest Treaty.

Therefore an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific plasmid/strain has been

deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

Claims 7-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding a polypeptide with SEQ ID NO:1 or 2 and having a specific protease activity, vectors and host cells comprising said polynucleotide and a method of making the polypeptide using the host cell comprising said polynucleotide, does not reasonably provide enablement for any such polynucleotide which encodes a polypeptide that is at least 90% identical to SEQ ID NO:1 or 2 and encoding a polypeptide having protease activity, vectors and host cells comprising said polynucleotide and a method of making the polypeptide using the host cell comprising said polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 7-34 are so broad as to encompass any polynucleotide that encodes a polypeptide that is at least 90% identical in its sequence to SEQ ID NO:1 or 2 vectors and host cells

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comprising said polynucleotide and a method of making the polypeptide using the host cell comprising said polynucleotide. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by said polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in said encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. Simply put, applicants have not taught those skilled in the art as to where exactly on the polynucleotide sequence encoding SEQ ID NO:1 or 2, specific nucleotides can be modified (i.e., by insertion, deletion or substitution), and how to select those modified sequences in order to arrive at those that encode the polypeptide having the specific activity of SEQ ID NO:1 or 2. The specification is limited to teaching the use of the polynucleotide with SEQ ID NO:3 or 4 to encode the polypeptide with SEQ ID NO:1 or 2 and use it as a specific protease but provides no guidance with regard to the making of variants and mutants or with regard to the other uses indicated above. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref. U, Form-892), the claimed invention

would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a polynucleotide sequence leading to variants or mutants through which amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any encoded protein, and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide encoding a polypeptide with 90% sequence identity to SEQ ID NOS:1 or 2 because the specification does not establish: (A) regions of the polynucleotide structure which may be modified without affecting its activity of encoding the polypeptide having the specific protease activity; (B) the general tolerance of polynucleotides encoding such proteases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide on the polynucleotide encoding said protease with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope Application/Control Number: 10/784,870

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of the claims broadly including polynucleotides with an enormous number of nucleotide modifications to the polynucleotides encoding SEQ ID NOS: 1 or 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

## **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-20 of U.S. Patent No. 6,376,227 and claims drawn to "a gene" in copending applications 10/456479, 10/820712, 10/820714, 11/235249,11/318576. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the

reference claim. See, e.g., In re Berg, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 7-34 of the instant application and claims 4-20 of the reference patent and claims drawn to "a gene" of the copending applications are all directed to polynucleotides encoding polypeptides that have at least 90% sequence identity with SEQ ID NO:1 or 2 (see enclosed sequence alignments). Among all the different polynucleotides claimed in the instant application and in the reference patent and copending applications a number of polynucleotides are identical to one another. The portion of the specification (and the claims) in the reference patent and copending applications that supports the recited polynucleotides includes several embodiments that would anticipate the polynucleotides and the vectors an host cells claimed in claims 7-34 herein. Claims 7-34 of the instant application listed above cannot be considered patentably distinct over claims 4-20 of the reference patent and claims of the copending applications when there is specifically recited embodiment that would anticipate mainly claims 7-34 of the instant application. Alternatively, claims 7-34 cannot be considered patentably distinct over claims 4-20 of the reference patent and claims of the copending applications when there is specifically disclosed embodiment in the reference patent and reference applications that supports claims 4-20 of that patent (and said applications) and falls within the scope of claims 7-34 herein because it would have been obvious to one having ordinary skill in the art to modify claims 4-20 of the reference patent and the claims drawn to a "gene" in the cop[ending applications by selecting a specifically disclosed embodiment that supports those claims. One of ordinary skill in the art would have been motivated to do this

because that embodiment is disclosed as being a preferred embodiment within claims of the reference patent and applications.

## Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Manjunath N. Rao, Ph.D.

Primary Examiner
Art Unit 1652

May 26, 2006

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CURRENT APPLICATION NUMBER: US/10/456,479
CURRENT FILING DATE: 2003-06-09
PRIOR APPLICATION NUMBER: JP 2002-186387
PRIOR PILING DATE: 2002-06-26
PRIOR APPLICATION NUMBER: JP 2002-304232
PRIOR PILING DATE: 2002-10-18
NUMBER OF ESQ ID NOS: 16
SOPTWARE: Patentin version 3.1
SEQ ID NO 4
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APPLICANT: SUMITOMO, NOBUYUKI
APPLICANT: NOMURA, MASATUMI
APPLICANT: KOBAYASHI, TOHRU
TITLE OF INVENTION: ALKALINE PROTEASE
FILE REFERENCE: 238700US0
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APPLICANT: SHIKATA, SHITSUW
APPLICANT: NOWURA, MASAFUMI
TITLE OF INVENTION: ALKALINE PROTEASE
FILE REFERENCE: 0327-0832-0PCT
CURRENT APPLICATION NUMBER: US/10/784,870
CURRENT FILING DATE: 2004-02-24
PRIOR APPLICATION NUMBER: US/99/509,814A
PRIOR APPLICATION NUMBER: PCT/JP98/04528
PRIOR APPLICATION NUMBER: PCT/JP98/04528
PRIOR FILING DATE: 1998-10-07
PRIOR FILING DATE: 1998-10-07
PRIOR PRILING DATE: 1997-06-08
NUMBER OF SEQ ID NOS: 24
                                                                                                    Query Match
Best Local Similarity 93.3
Conservative
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APPLICANT: TAKAIWA, MIKIO
APPLICANT: OKUDA, MITSUY
APPLICANT: SAEKI, KATSUH
APPLICANT: KUBOTA, HIROM
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                                                                                                                                                                                                                                                                                 SEQ ID NO 6
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SAEKI, KATSUHISA
KUBOTA, HIROMI
HITOMI, JUN
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Pred. No. 8.7e-261;
0; Mismatches 43;
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                                                            Query Match
Best Local Similarity
Matches 597; Conserv
                                                                                                                     SEQ ID NO 3
LENGTH: 640
TYPE: PRT
ORGANISM: Bacillus sp. KSM-KP43
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APPLICANT: KAO CORPORATION
APPLICANT: Okuda, Mitsuyos
                                                                                                                                                                                                                                                                                                                                                           Sequence 3, Application US/10820712A
Publication NO. US20050026804A1
                                                                                                                                                                     TITLE OF INVENTION: ALKALINE PROTEASE FILE REFERENCE: 251701-US0
CURRENT APPLICATION NUMBER: US/10/820,712A
CURRENT FILING DATE: 2004-04-09
PRIOR APPLICATION NUMBER: 2003-106708
PRIOR FILING DATE: 2003-04-10
NUMBER OF SEQ ID NOS: 23
SOFTWARE: Patentin version 3.2
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Izawa, Yoshifumi
Kobayashi, Tohru
Koyama, Shingo
Sato, Tsuyoshi
            MRXXXXVPLSVLSAAAILSTVALXNPSAGXARXFDLDFKGIQTTTDXXGFSKQXQTGAAA 60
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                                                                        Score 3029; DB 5;
Pred. No. 8.7e-261;
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; LENGTH: 640
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                 MRXKKKVELSVLSAAAILSTVALXNESAGXARXEDLDEKGIQTTIDXXGESKQXQTGAAA 60
MRKKKKVFLSVLSAAAILSTVALSNPSAGGARNFDLDFKGIQTTTDAKGFSKQGQTGAAA 60
                                                99.0%;
larity 93.3%;
Conservative
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Sequence 3, Application US/10820714A

Publication No. 1820050214922A1

Publication No. 1820050214922A1

PRESENTAL-ENFORMATION:
APPLICANT: KOC CORPORATION

APPLICANT: Kobayashi, Tohru

APPLICANT: Sumitomo, Nobuyuki

APPLICANT: Statura, Yasushi

APPLICANT: Statura, Yasushi

APPLICANT: Statura, Yasushi

APPLICANT: Stato, Tsuyoshi

ITITLE OF INVENTION: ALKALINE PROTEASE

FILE REFERENCE: 251697US0

CURRENT APPLICATION NUMBER: US/10/820,714A

CURRENT APPLICATION NUMBER: 2003-106709

PRIOR APPLICATION NUMBER: 2003-106709

PRIOR PRILING DATE: 2003-04-10

NUMBER OF SEQ ID NOS: 24

SOPTWARE: Patentin version 3.2
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                                                                                                                            gp.
                                                                                                                               KSM-KP43
Score 3029; DB 5;
Pred. No. 8.7e-261;
0; Mismatches 43;
                                               Length 640;
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